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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,396	08/30/2001	Nancy Allbritton	P677c	4207

7590

06/25/2003

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EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/945,396

Applicant(s)

ALLBRITTON ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-102 is/are pending in the application.
- 4a) Of the above claim(s) 82-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 1, claims 48-81 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-51, 53, 55, 68, 72-74, 78-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations in claims 50-51, 78-80 are directed to a span of time that the contents of a cell were collected, offers no support in the instant specification. Claim 53, is directed to the limitation of stopping a reaction of biochemical reactants disrupted from the cell to permit an analysis of the reactants in the state which existed at the time of disruption of the cell lacks support in the instant specification. Claim 55, is directed to the limitation of positioning the cell by laser microbeam optical tweezers lacks support in

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the instant specification. Claim 68, is directed to the collection of substrates of a lysed cell by a method of electroosmotic fluid flow lacks support in the instant specification.

Claims 72-74, are directed to a means of collecting the substrate by a means of a microlumen of a micropipette, microfabricated channel lacks support in the instant specification. Applicant is invited to show support in the instant specification regarding the instant claimed limitations.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 48-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 48 recites the limitation "the catalysis" in step (d). There is insufficient antecedent basis for this limitation in the claim. Also, parts (c) and (d) are confusing because it is not clear if the label binds to the substrate (part (c)) or to the altered substrate (part (d)).

6. Claims 49, 64-69, 77-80 recites the limitation "lysed cell or cellular component" and "lysed said cell". There is insufficient antecedent basis for this limitation in the claim.

7. Claim 49 recites the limitation "said contents" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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8. Claim 49 recites the limitation "when collecting at least a portion of said substrate", vague because it is unclear which substrate applicant is referring, the detected altered substrate or the detected unaltered substrate?

9. Claim 52 recites the limitation "relatively positioning" in line 1, is indefinite because it is unclear as to what is meant by that limitation. Also, the term "identifying" in line 2, is indefinite because it is unclear as to what is being identified. Please clarify.

10. Claim 53 recites the limitations "the state" and "the time in lines 4 and 5. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 78 recites the limitation "said accessible substrate" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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14. Claims 48-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,335,201.

Although the conflicting claims are not identical, they are not patentable distinct from each other because both inventions are drawn to a method of measuring intracellular chemical activity of species within a cell or cellular component.

The instant claims 48-81 of the application measures intracellular chemical activity of a single species of a molecule of a cell or cellular component. A substrate is selected to view catalysis of a reaction between the species and the substrate that produce altered substrates. Disrupting the cell or cellular component liberates the contents of the cell. The contents of the cell comprising the substrate and altered substrate molecules are collected and analyzed for determining the activity of chemical reactions between the altered substrate molecules and the substrates molecules. Contents of the cells or cellular components are collected and separated by electrophoresis.

In Patent No. 6,335,201 the patented claims 1-19 are drawn to a method involving measuring the activity of intracellular chemical reactions in a cell or portions or groups of cells with method steps of providing substrate molecules with a reporting label to chemically react within the cell to produce altered substrate molecules. The substrate molecules are liberated from the cell and the label is detected to identify the substrate molecules and altered substrate molecules. The contents of the cell are collected and separated in an electrophoretic column or channel.

The instant claims in the application differs only in the addition of a laser generated shockwave and the collection of the contents of a cell within microseconds after liberation. The instant claims of the application also differs in the addition of a micromanipulator to aid in the positioning of the microlumen and the cell or cellular component so that lysis can be performed.

However, the instant claimed invention is encompassed by the Patent #6,335,201 because the patented claims are directed to several means of liberating the cell, (see claim 11) such as electrical, mechanical and chemical. The instant specification of the patented claims lists one example of cell liberation as being a "laser shock wave" (col. 14, lines 1-6). Wherein, the present claims of the instant application is directed to a specific embodiment "laser shock wave" this is of a general liberation technique that is encompassed by the instant Patent#6,335,201. The instant claimed the Patent #6,335,201 further encompasses invention because the broad limitation in claim 1 that recites, "liberating the substrate molecules from the cell or groups of cells" is silent with respect to the devices used to accomplish this method. Wherein the present claims of the instant application is directed to specific limitations such as devices used to position the cells to perform lysis that include using a micromanipulator to position the microlumen and the cells. However, the instant specification of Patent #6,335,201 reveal those specific devices as being a micromanipulator that is used to position the cells and the capillary lumen so that lysis can be performed (see col. 14, lines 25-35). With respect to the time of analysis cited in claims 50-51, 77-80, this is

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viewed as mere optimization of the prior art methods. Absent evidence to the contrary, the time would have been modified to produce the optimal working assay conditions.

Conclusion

15. No claims are allowed.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Fu-Tai A. Chen (USP5,571,680) discloses a homogeneous immunoassay and enzyme-substrate assays which use capillary electrophoresis and fluorescent detection systems for quantitating the concentration of analyte in a sample.

B. Luzzi et al teaches a method for localized sampling of cytoplasm from *Xenopus* Oocytes for capillary electrophoresis and measuring the activity of the enzyme beta-galactosidase in the cell (reference no. 28 on the information Disclosure Statement filed November 15, 1999).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123.



Deborah A. Davis

CM1, 7D16

June 23, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800 / 441